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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,338	06/25/1999	SPIROS FOTINOS	1581/120	3768

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ALLEN BLOOM  
C/O DECHERT  
PRINCETON PIKE CORPORATION CENTER  
P.O. BOX 5218  
PRINCETON, NJ 08543-5218

EXAMINER
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WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/340,338

Applicant(s)

FOTINOS, SPIROS

Examiner

Todd D Ware

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4-2-03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

Receipt of request for extension of time (granted) and amendment both filed 4-2-03 is acknowledged. Claims 1, 3-5, 7-23, 26-36, and 39-41 have been canceled and new claims 42-103 have been added as requested. Claims 42-103 are pending.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. **Claims 42-43, 47-48, 50-51, and 55-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Denzer (6,007,836; hereafter '836). Webster's (1988) is relied upon for providing the meaning of the term "rigid."**

3. '836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52) and '836 also discloses "anchoring the transdermal patch to the skin of the user" (C 8, L 3-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word "rigid" in the instant

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claims. Therefore, Webster's New World Dictionary (1988), which defines rigid as "not moving; firmly fixed," is relied upon to provide the meaning of the term. '836 also discloses 2-layered embodiments of the vasodilator system where one of the layers is a backing layer (C 9, I 49-57; C 10, L 30-32). Column 15, lines 22-30, of '836 discloses that the patch does not have a backing layer when used in conjunction with a condom. Thus, upon application of the patch, the release liner is removed and there is no backing layer. Accordingly, '836 meets the limitations of the instant claims.

#### ***Response to Arguments***

4. Applicant's arguments filed 4-2-03 have been fully considered but they are not persuasive. Applicant argues that the instant claims overcome '836 since they exclude a release liner and a backing layer while '836 specifically requires a release liner and a backing layer. However, '836 discloses 2-layered embodiments of the vasodilator system where one of the layers is a backing layer (C 9, I 49-57; C 10, L 30-32). Column 15, lines 22-30, of '836 discloses that the patch does not have a backing layer when used in conjunction with a condom. Thus, upon application of the patch, the release liner is removed and there is no backing layer. Accordingly, '836 meets the limitations of the instant claims.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**6. Claims 42-44, 47-48, 50-57, 60-66, and 80-85 are rejected under 35**

**U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836).**

**Webster's (1988) is relied upon for providing the meaning of the term "rigid."**

7. '836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. '836 also discloses "anchoring the transdermal patch to the skin of the user" (C 8, L 3-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word "rigid" in the instant claims. Therefore, Webster's New World Dictionary (1988), which defines rigid as "not moving; firmly fixed," is relied upon to provide the meaning of the term. '836 also teaches 2-layered embodiments of the vasodilator system where one of the layers is a backing layer (C 9, L 49-57; C 10, L 30-32). Column 15, lines 22-30, of '836 discloses that the patch does not have a backing layer when used in conjunction with a condom. Thus, it would have been obvious to one skilled in the art at the time of the invention that upon application of the patch with a condom, the release liner is removed

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and there is no backing layer. Accordingly, '836 meets the limitations of the instant claims. Furthermore, Applicant has not established the criticality of the limitations excluding a release liner and a backing layer. Pages 11-12 of the instant specification specifically teach that a release liner and backing layer are applied to the delivery device.

**8. Claims 45, 58, 67, 69-76, 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Yamamura et al (5,914,118; hereafter '118). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

9. '836 is relied upon for all that it teaches as stated previously and inclusion of karaya as an adhesive. '836 does not teach the limitation where polyvinylpyrrolidone is included in the device.

10. '118 is relied upon for teaching equivalence of polyvinylpyrrolidone and karaya adhesives in transdermal formulations.

11. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying herein.

**Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over '7,836; hereafter '836) in view of Postaire (FR 2710649; hereafter '649).**

**Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

13. '836 is relied upon for all that it teaches as stated previously. '836 does not teach the limitation where the filmogenic polymer is a plant protein.

14. '649 is relied upon for teaching a transdermal patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1). Such a gel allows optimization of the adhesive properties for the patch.

15. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to formulate the polymer films of '836 with gliadin with the motivation of adjusting the adhesive properties of the device of '836.

16. **Claims 49 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Place et al (5,773,020; hereafter '020). Webster's (1988) is relied upon for providing the meaning of the term "rigid."**

17. '836 is relied upon for all that it teaches as stated previously. '836 does not teach the limitation where the active agent is misoprostol.

18. '020 teaches that misoprostol treats erectile dysfunction.

19. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include misoprostol in the formulation of '836 for treatment of erectile dysfunction with the motivation that misoprostol may be more readily available or more tolerated than the actives of '836.

20. **Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in combination with Yamamura et al (5,914,118; hereafter '118) and further in combination with Place et al (5,773,020; hereafter '020). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

21. '836 and '118 are relied upon for all that it teaches as stated previously. Neither reference teaches the limitation where the active agent is misoprostol.

22. '020 teaches that misoprostol treats erectile dysfunction.

23. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include misoprostol in the combined formulation of '836 and '118 for treatment of erectile dysfunction with the motivation that misoprostol may be more readily available or more tolerated than the actives of '836.

24. **Claims 86-89, 91-94, 99-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Smith et al (6,001,380; hereafter '380). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

25. '836 is relied upon for all that it teaches as stated previously. It is further noted that the compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not teach wetting the penile surface prior to application.



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26. '380 is relied upon for teaching wetting skin prior to application of transdermal devices to aid in adhesion of the device and release of active agents.

27. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to wet the surface to which the device of '836 is applied with the motivation of aiding in adhesion of the device and release of active agents.

28. **Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in combination with Smith et al (6,001,380; hereafter '380) and further in combination with Place et al (5,773,020; hereafter '020). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

29. '836 and '380 are relied upon for all that they teach as stated previously. Neither reference teaches the limitation where the active is misoprostol.

30. '020 teaches that misoprostol treats erectile dysfunction.

31. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include misoprostol in the combined process of '836 and '380 for treatment of erectile dysfunction with the motivation that misoprostol may be more readily available or more tolerated than the actives of '836.

32. **Claims 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in combination with Smith et al (6,001,380; hereafter '380) and further in combination with Postaire (FR 2710649; hereafter**

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**'649). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

33. '836 and '380 are relied upon for all that they teach as stated previously. Neither reference teaches the limitation where the filmogenic polymer is a plant protein.

34. '649 is relied upon for teaching a transdermal patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1). Such a gel allows optimization of the adhesive properties for the patch.

35. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to formulate the polymer films of '836 with gliadin with the motivation of adjusting the adhesive properties of the device of '836.

36. **Claims 92, 95, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in combination with Smith et al (6,001,380; hereafter '380) and further in combination with Yamamura et al (5,914,118; hereafter '118). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."**

37. '836 and '380 are relied upon for all that they teach as stated previously. It is further noted that '836 teaches inclusion of karaya as an adhesive. Neither reference teaches the limitation where polyvinylpyrrolidone is included in the device.

38. '118 is relied upon for teaching equivalence of polyvinylpyrrolidone and karaya adhesives in transdermal formulations.

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39. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

### ***Response to Arguments***

40. Since applicant's arguments are primarily directed toward overcoming the primary reference '836, stating that the secondary references do not overcome the deficiencies of '836, the response to arguments under 35 USC 103(a) will be addressed concurrently. Applicant's arguments filed 4-2-03 have been fully considered but they are not persuasive.

41. Applicant argues that the instant claims overcome '836 since they exclude a release liner and a backing layer while '836 specifically requires a release liner and a backing layer. However, '836 discloses 2-layered embodiments of the vasodilator system where one of the layers is a backing layer (C 9, I 49-57; C 10, L 30-32). Column 15, lines 22-30, of '836 discloses that the patch does not have a backing layer when used in conjunction with a condom. Thus, upon application of the patch, the release liner is removed and there is no backing layer. Accordingly, '836 meets the limitations of the instant claims. Furthermore, Applicant has not established the criticality of the limitations excluding a release liner and a backing layer. Pages 11-12 of the instant specification specifically teach that a release liner and backing layer are applied to the delivery device.

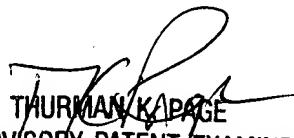
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**Conclusion**

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

tw  
June 16, 2003